

## **REMARKS**

### **The Amendments**

Claims 1-24, 26, 27, 32-36 and 38 are canceled. Claim 25 is amended to recite that the complex is in a granulate preparation, i.e., in a granulate form (see, e.g., page 6, lines 4-10, of the specification) and to recite that the one or more excipient(s) is/are optional (see, e.g., page 7, lines 28-31, of the specification). Claim 37 is amended to incorporate the substance of claim 38 and claims 37 and 42 are amended to clarify the "granulation conditions" term. New dependent claims are added.

To the extent that the amendments avoid the prior art or for other reasons related to patentability, competitors are warned that the amendments are not intended to and do not limit the scope of equivalents which may be asserted on subject matter outside the literal scope of any patented claims but not anticipated or rendered obvious by the prior art or otherwise unpatentable to applicants. Applicants reserve the right to file one or more continuing and/or divisional applications directed to any subject matter disclosed in the application which has been canceled by any of the above amendments.

### **Priority Document**

The certified priority document for applicants' prior claim to priority is attached.

### **The Obviousness-type Double Patenting Rejection**

The obviousness-type double patenting rejection of claims 1-13 and 22 is rendered moot

by the cancellation of the rejected claims.

### **The Claim Objection**

The objection to claims 10-13 is rendered moot by the cancellation of the objected to claims.

### **The Rejection under 35 U.S.C. §112, second paragraph**

The rejection of claims 8, 9, 26-27 and 37-46 is rendered moot, in part, and traversed, in part.

Claims 8, 9, 26 and 27 are canceled.

Regarding the "derivatives" term, the claims remaining which recite "derivatives" specify that such derivatives are "alkylated or acylated derivatives;" see, claims 51 and 52 and the specification at page 10, lines 27-29. Thus, the manner of derivatization is clear and definite.

Regarding the "granulation conditions" term, the method claims containing this term now recite the positive step of "granulating." Thus, the claims recite a positive step providing the context for the "granulation conditions" term. It should be apparent that "granulation conditions" are conditions which allow the granulating step to occur. The specification clearly describes the meaning of the term "granulate preparation" which is the result of the granulating step, see, e.g., page 6, lines 4-10; page 13, lines 17-20; page 16, lines 12-25, and Example 5; of the specification. The "granulation conditions" which would be used to obtain such a result would be clear to one of ordinary skill in the art based on these disclosures and, thus, the term is definite.

### **The Rejection under 35 U.S.C. §103**

The rejection of claims 1-34 under 35 U.S.C. §103, as being obvious over Backensfeld (U.S. Patent No. 5,798,338) in combination with Parikh (U.S. Patent No. 6,228,399), Pitha (U.S. Patent No. 4,596,795) and Krattenmacher (*Contraception* article) is respectfully traversed.

Initially, it is noted that the subject matter of method claims 37 and 42 (and claims dependent thereon) is not subject to the art rejection. It is believed that the 35 U.S.C. §112, second paragraph, rejection of these claims is overcome and, therefore, these claims, at least, are in condition for allowance.

Backensfeld relates, in general, to compositions comprising complexes between ethinylestradiol and  $\beta$ -cyclodextrins. It generically mentions that the complex can be provided in the form of a granulate, among other forms; see, col. 2, lines 45-49. It discloses in one example, only, a composition comprising such a complex in granulated form (Example 3). In Example 3, the granulated form of the complex was manufactured using a granulation liquid including the binder, polyvinylpyrrolidone (PVP 25000). It can be calculated that the resulting composition comprised about 4.9 % w/w of the PVP. Compare the language in the instant claims restricting the content of PVP in the claimed invention; see also, the paragraph bridging pages 7-8 of the specification discussed the discovered undesired aspect of higher amounts of PVP.

The Office Action states that the burden is upon applicant to show a novel or nonobvious difference between the claims and the prior art. In fact, applicants have provided such a showing on the record that compositions comprising a granulated preparation of a complex according to Example 3 of Backensfeld have poor stability with respect to the concentration of

ethinylestradiol. Example 1 of the present patent application prepares and tests for stability a composition according to Example 3 of Backensfeld. The tests show that, following storage at 40°C for 12 months, only 76% of the initial content of ethinylestradiol is present in the granulated composition. See the data for tablet A in table 1.3 of the specification. Thus, it has been shown that the only specifically described granulate composition of Backensfeld does not, inherently or otherwise, meet the claim recitation regarding estrogen stability, i.e., "estrogen is in an amount of at least 85% w/w in relation to the initial content of said estrogen after storage for 12 months at 40°C and 75% relative humidity (RH)." In contrast, the stability of a composition according to the present invention in a side-by-side test is shown to be stable. Nearly 100% of the initial content of ethinylestradiol is maintained in a composition of the present invention following storage at identical test conditions, see data for tablet E in table 1.3 of Example 1.

The Office Action further implies that, if the humidity conditions are met by the Backensfeld compositions, the stability meeting the instant claim recitations would also be met. As shown above, however, this is not the case. Humidity is a factor but not the only factor. For example, the nature and amount of excipient is also a factor, as discovered by applicants; see, e.g., page 15, line 30, to page 16, line 10, of the instant specification.

Accordingly, it is urged that Backensfeld fails to inherently teach or suggest a composition meeting the stability recitation of the instant claims.

The secondary references were cited for their teachings regarding dependent claim recitations and provide no teachings which would suggest modification of Backensfeld in a manner which would suggest the instant claims. The secondary references fail to teach the stability aspect as recited in the instant claims or the means for achieving this stability. Even if

Pitha and Krattenmacher would suggest combining a progesterone, such as drospirenone, into the Backensfeld compositions, such would not result in or suggest applicants' invention in terms of the stability recitations of the claims. Similarly, even if Parikh suggested micronizing the active agents, such as drospirenone, and providing them in the Backensfeld compositions, such would not result in or suggest applicants' invention in terms of the stability recitations of the claims.

As an additional distinguishing basis – with respect to claims 37, 47 and 64 – neither Backensfeld or the other references teach or suggest restricting or minimizing the amount of excipients which have oxidizing potentials such as polyvinylpyrrolidone (PVP). Applicants have also discovered the advantage of avoiding excess amounts of such oxidizing compounds to enhance stability. This is obviously unrecognized in the art since Backensfeld itself discloses the use of a higher amount of PVP.


None of the references of record teach or suggest providing compositions wherein an estrogen is stabilized according to the instant claims, e.g., by providing a granulated form of the complexes and/or by restricting or minimizing the amount of excipients which have oxidizing potentials greater than or similar to PVP. Compare, for example, the disclosure at page 15, line 30, to page 16, line 10, of the instant specification.

For all of the above reasons, it is urged that the references, considered as a whole, fail to render the claimed invention obvious to one of ordinary skill in the art. Thus, the rejection under 35 U.S.C. § 103 should be withdrawn.

It is submitted that the claims are in condition for allowance. However, the Examiner is kindly invited to contact the undersigned to discuss any unresolved matters.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

  
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